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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,279	07/15/2005	Helga Schleenhain	82182	3461

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EXAMINER	
JEAN-LOUIS, SAMIRA JM	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
07/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,279	SCHLEENHAIN, HELGA	
	Examiner	Art Unit	
	SAMIRA JEAN-LOUIS	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/18/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This Office Action is in response to the amendment submitted on 04/18/08. Claims 1 and 3 are currently pending in the application, with claim 2 having being cancelled. Accordingly, claims 1 and 3 are being examined on the merits herein.

Receipt of the aforementioned amended claims is acknowledged and has been entered.

Applicant's argument with respect to the rejection of claims 1-3 under 35 U.S.C. § 101 is acknowledged. Because applicant has amended the claims, such arguments are now moot. As a result, the rejection of claims 1-3 under 35 U.S.C. § 101 is withdrawn.

Applicant's argument with respect to the rejection of claims 1-3 under 35 U.S.C. § 112, second paragraph is acknowledged. Because applicant has amended the claims, such arguments are now moot. As a result, the rejection of claims 1-3 under 35 U.S.C. § 112, second paragraph is withdrawn.

Applicant's argument with respect to the rejection of claims 1-3 under 35 U.S.C. § 102 (b) is acknowledged. Because applicant has amended claims 1 and 3 and cancelled claim 2, such arguments are now moot. As a result, the rejection of claims 1-3 under 35 U.S.C. § 102 (b) is withdrawn.

Applicant's argument with respect to claims 1 and 3 as being patentable over Halama has been fully considered but is not found persuasive. Given the fact that the claims are newly presented and Examiner has yet to search the new claims, such arguments are moot. However, applicant's contention of the surprising finding of a lower reduced dosage of cinnarizine and dimenhydrinate of 2.5 compared to corresponding monotherapies of cinnarizine and dimenhydrinate individually and that the dosage combination is super additive synergism are not persuasive. Such arguments are not persuasive because applicant's own evidentiary support (i.e. Cirek et al.) explicitly teaches that the two active agents of the fixed combination -cinnarizine (20 mg per tablet) and dimenhydrinate (40 mg per tablet) (as taught by Halama) possess distinct pharmacological properties that complement one another synergistically. This conclusion suggests that the synergistic effect observed by applicant is inherently present in the product as the synergism exists due to the inherent interactive properties of the compounds. Thus, given that Halama teaches the exact same combination with the exact same dosage, such product will inherently possess the same synergistic properties.

Applicant's contention of the surprise finding of a reduced dosage (i.e. 2.5 times less) as more effective has been fully considered and are not persuasive. Again, Examiner points out that such reduced dosage is also present in Halama as it was well known in the art long before applicant's invention to administer the combination of 20 mg of cinnarizine and 40 mg of dimenhydrate. Interestingly, applicant's own specification reveals clinical studies previously performed utilizing dosages of 50 mg cinnarizine and 100 mg dimenhydrinate which were 2.5 times higher (see spec. pg. 8, study 1) than that used by Halama. Consequently, the teachings of Halama inherently teaches 2.5 times lower dosage as 20 mg cinnarizine and 40 mg dimenhydrinate is 2.5 times less than 50 mg cinnarizine and 100 mg dimenhydrinate. Moreover, Examiner would further like to point out that intended use in a product claim is not afforded any patentable weight. The intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the limitation of the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963)*. Thus, the intended use for dizziness is not afforded patentable weight.

For the foregoing reasons, the rejection of claims 1-3 under 102 (b) remains proper and is maintained. However, in view of applicant's amendment and cancellation of claim 2, the following modified 102 (b) Final rejection is being made.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Halama (Therapiewoche 35, pgs. 1422-1426, previously cited).

The inclusion of "for dizziness" in applicant's invention for the purpose of treating dizziness is an intended use and as such is not afforded patentable weight in a product claim. It is respectfully pointed out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the limitation of the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963).* Thus, the intended use for dizziness is not afforded patentable weight.

Halama teaches an Arlevert tablet product (i.e. combination of cinnarizine and dimenhydrinate) in the treatment of peripheral-vestibular and cerebral vertigo and the concomitant symptoms (see English abstract vs. instant claim 1). In particular, Halama

teaches a control therapy where a tablet formulation of Arlevert was given and vertigo endpoints were evaluated using a cranial topography method (see page 1424, column 3 and table 3). It is further noted that the tablet Arlevert is further composed of adjuvants and/or additives such as magnesium stearate. hypromellose, cellulose, etc...(German copy and see http://www.gelbe-liste.de). Importantly, Halama teaches that the combination therapy is more effective than monotherapy in tablet dosages containing 20 mg cinnarizine and 40 mg dimenhydrinate (see col. 1, pg. 1423).

Accordingly, the teachings of Halama anticipate claims 1 and 3.

Regarding the limitation of the dosage of cinnarizine and dimenhydrinate being reduced 2.5 times as compared to corresponding therapies with cinnarizine and dimenhydrinate individually, Examiner concludes that the product combination of Halama is 2.5 times less given applicant's own specification indicates that prior clinical studies were previously utilizing 50 mg cinnarizine and 100 mg dimenhydrinate, a dosage which were 2.5 times higher (see spec. pg. 8, study 1) than that used by Halama.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L./

Examiner, Art Unit 1617

07/13/2008

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617